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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,173	04/08/2004	Susan R. Webb	TSRI 536.1 C1	3667

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,173	WEBB ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-60,85-91 and 100-153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *33-60,85-91 and 100-153* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/715,231, which is a divisional of U.S. Application Serial Number 09/194,285, wich is a rule 371 continuation of PCT Serial Number PCT/US97/08697.

Claims 1-32, 61-84, and 92-99 have been canceled.

New claims 114-153 have been added.

Claims 33-60, 85-91 and 100-153 are currently pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 33-60 and 141-150; drawn to a synthetic antigen-presenting matrix for activating CD4+ T cells comprising a) a support, b) an extracellular portion of a MHC Class II heterodimer and c) an extracellular portion of at least one accessory molecule, classified in class 530, subclass 350.

II. Claims 85-91, 114-136 and 151, drawn to a method of producing a synthetic antigen matrix comprising A) providing an extracellular portion of a recombinant MHC Class II heterodimer, b) providing an extracellular portion of at least one recombinant accessory molecule, and c) linking the MHC Class II heterodimer and accessory molecule to a support, classified in class 530, subclasses 328 and 350.

III. Claims 100-103 and 152, drawn to a method for activating CD4+ T cells in vitro, comprising providing the matrix of claim 33, loading the MHC Class II heterodimer with a peptide and contacting the peptide-loaded cell matrix with the CD4+ T cells, separating the activated CD4+ T cells from the APC, adding the activated CD4+ T cells to an acceptable carrier to form a suspension, and administering the suspension to a patient, classified in class 424, subclass 193.1.

IV. Claims 137-140 and 153, drawn to a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting matrix according to claim 33 with a peptide library in vitro, contacting the peptide loaded MHC Class II heterodimer with CD4+ T cells, separating the activated CD4+ T cells from the APC, adding the activated CD4+ T cells to an acceptable carrier to form a suspension, and administering the suspension to a patient, classified in class 424, subclass 193.1 and class 436, subclass 536.

2. The inventions are distinct, each from the other because of the following reasons:

Groups II-IV are drawn to distinct methods because the endpoints of Group II and the endpoint of Groups III/IV are different. Though the endpoints of Groups III and IV are the same, they differ in their process steps, the former comprising loading the MHC Class II heterodimer with one peptide, the latter

comprising loading the MHC Class II heterodimer with a peptide library in vitro. Therefore, Groups II-IV are patentably distinct, each from the other.

Groups I and III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the synthetic antigen presenting matrix, can be used in a method for screening analogs of peptide epitopes, as well as in a method for activating CD4+ T cells in vitro.

Groups II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the synthetic antigen presenting matrix, can be made by immunoprecipitation of lysed antigen presenting cells with an antibody coupled to Protein A beads.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification Further, a prior art search requires a literature search. It is an undue burden for the Examiner to search more than one invention and restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species:

A) If Group I is elected, the applicant is further required under 35 U.S.C. 121:
- i) to elect a synthetic antigen presenting matrix comprising a specific support, such as a cell fragment as recited in claim 34, or a cell as recited in claim 35, or a liposome as recited in claim 37, or a solid surface as recited in claim 38,
- ii) to elect a synthetic antigen presenting matrix comprising a specific combination of specific accessory molecule(s), such as a costimulatory molecule as recited in claim 44, or an adhesion molecule as recited in claim 46, or a survival molecule as recited in claim 48.
  - a) if a costimulatory molecule is elected, then applicant is further required to elect a specific costimulatory molecule such as B7.1 as recited in claim 45,
  - b) if an adhesion molecule is elected, then applicant is required to elect a specific adhesion molecule such as ICAM-1 as recited in claim 47,
  - c) if a survival molecule is elected, then applicant is further required to elect a specific survival molecule such as CD70 as recited in claim 49.

B) If Group II is elected, the applicant is further required under 35 U.S.C. 121:

i) to elect a method of producing a synthetic antigen presenting matrix comprising a specific support, such as a cell fragment as recited in claim 114, or a cell as recited in claim 115, or a liposome as recited in claim 119, or a solid surface as recited in claim 120,

a) If a cell is elected, then applicant is required to elect a specific cell, such as an insect cell as recited in claim 116,

i) if an insect cell is elected, applicant is further required to elect a specific insect cell such as drosophila as recited in claim 117,

ii) to elect a method of producing a synthetic antigen presenting matrix comprising a specific combination of specific accessory molecule(s), such as a costimulatory molecule as recited in claim 86, or an adhesion molecule as recited in claim 88, or a survival molecule as recited in claim 90,

a) if a costimulatory molecule is elected, then applicant is further required to elect a specific costimulatory molecule such as B7.1 as recited in claim 87,

b) if an adhesion molecule is elected, then applicant is required to elect a specific adhesion molecule such as ICAM-1 as recited in claim 89,

c) if a survival molecule is elected, then applicant is further required to elect a specific survival molecule such as CD70 as recited in claim 91.

C) If Group III or IV is elected, the applicant is further required under U.S.C. 121:

i) to elect a method for activating CD4+ T cells in vitro comprising a synthetic antigen presenting matrix comprising a specific support, such as a cell fragment as recited in claim 34, or a cell as recited in claim 35, or a liposome as recited in claim 37, or a solid surface as recited in claim 38,

ii) to elect a method for activating CD4+ T cells in vitro comprising a synthetic antigen presenting matrix comprising a specific combination of specific accessory molecule(s), such as a costimulatory molecule as recited in claim 44, or an adhesion molecule as recited in claim 46, or a survival molecule as recited in claim 48,

a) if a costimulatory molecule is elected, then applicant is further required to elect a specific costimulatory molecule such as B7.1 as recited in claim 45,

b) if an adhesion molecule is elected, then applicant is required to elect a specific adhesion molecule such as ICAM-1 as recited in claim 47,

c) if a survival molecule is elected, then applicant is further required to elect a specific survival molecule such as CD70 as recited in claim 49,

iii) to elect a method for activating CD4+ T cells in vitro comprising a synthetic antigen presenting matrix comprising a specific peptide if Group III is elected, or elect a specific peptide library if Group IV is elected.

5. The species are independent or distinct for the following reasons:

A) Specific supports, each encompass compositions and physical structures with unique properties.

B) Specific accessory molecules differ with respect to their biophysical structure and function.

C) Specific peptides differ with respect to their amino acid sequences and their biophysical structure and function.

D) Peptide libraries differ with respect to the amino acid sequences and/or length of the encompassed peptides.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 33-60, 85-91,100-103, and 114-140 are generic, in at least one aspect.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. RV
Patent Examiner
December 29,2006

David A Saunders
DAVID A. SAUNDERS
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